

Patient Information

Rx only

SERZONE[®]

(nefazodone hydrochloride)

Tablets

Read this information completely before using SERZONE. Read the information each time you get more medicine. There may be new information. This leaflet provides a summary about SERZONE and does not include everything there is to know about your medicine. This information is not meant to take the place of talking with your doctor.

What is the most important information that I should know about SERZONE?

Rarely, people who take SERZONE can develop serious liver problems. **If you get any of the following symptoms while taking SERZONE, call your doctor right away** because you may be developing a liver problem:

- Yellowing of the skin or whites of eyes (jaundice)
- Unusually dark urine
- Loss of appetite that lasts several days or longer
- Nausea
- Abdominal (lower stomach) pain

People who currently have liver problems should not take SERZONE.

What is SERZONE?

SERZONE (pronounced sir-ZONE) is a medicine used to treat depression. SERZONE is thought to treat depression by correcting an imbalance in the amounts of certain natural chemicals, such as serotonin and norepinephrine, which are in your brain.

Who should not take SERZONE?

Do **not** take SERZONE if you

- are allergic to SERZONE or the related medicine Desyrel[®] (trazodone).
- are taking Seldane[®] (terfenadine), an antihistamine; Hismanal[®] (astemizole), an antihistamine; Propulsid[®] (cisapride), used for heartburn; Halcion[®] (triazolam), used for insomnia; Orap[®] (pimozide), used to treat Tourette's syndrome; or Tegretol[®] (carbamazepine), used to control seizures.

- currently have liver problems.
- are taking or have taken within the last 14 days one of the medicines for depression known as monoamine oxidase inhibitors (MAOIs), such as Nardil® or Parnate®.

Be sure to tell your doctor if you

- have ever had liver problems;
- are taking *any* other medicine, vitamin supplement, or herbal remedy, including those sold without a prescription (over-the-counter);
- have heart problems or have had a heart attack or stroke;
- have had manic episodes (extreme agitation or excitability);
- have ever attempted suicide;
- have had convulsions (seizures);
- are pregnant or breast-feeding.

How should I take SERZONE?

- Take SERZONE at the same time every day exactly as prescribed by your doctor. You may take SERZONE with or without food.
- It may take a while for you to feel that SERZONE is working. You may not feel the full effect for several weeks. Once you feel better, it is important to keep taking SERZONE as directed by your doctor.
- If you miss a dose of SERZONE, skip that dose and continue with your regular schedule. Never take 2 doses at the same time.
- If you think that you have taken more SERZONE than prescribed, contact your doctor, local poison control center, or emergency room right away.

What should I avoid while taking SERZONE?

- Do not drive or operate possibly dangerous machinery (such as an automobile, power mower, or power tool) or participate in any hazardous activity that requires full mental alertness until you know how SERZONE affects you.
- Before taking SERZONE, tell your doctor about *any* medicines you are taking, including vitamin supplements, herbal remedies, and any non-prescription (over-the-counter) medicines. Some of these medicines may affect how SERZONE works and should not be used in combination without talking to your doctor.
- Do not drink alcoholic beverages while taking SERZONE.
- Tell your doctor if you are pregnant, planning to become pregnant, or become pregnant while taking SERZONE. It is not known whether SERZONE can harm your unborn baby.

- Talk with your doctor before taking SERZONE if you are breast-feeding. It is not known whether SERZONE can pass through your breast milk to the baby.

What are the possible side effects of SERZONE?

The most common side effects of SERZONE are sleepiness, dry mouth, nausea, dizziness, constipation, weakness, lightheadedness, problems with vision, and confusion.

Call your doctor right away if you have any of the following side effects:

- Yellowing of the skin or whites of eyes (jaundice)
- Unusually dark urine
- Loss of appetite that lasts several days or longer
- Severe nausea
- Abdominal (lower stomach) pain
- Rash or hives
- Seizure (convulsion)
- Fainting
- Erection that lasts too long

Tell your doctor right away about any side effects that you have or discomfort that you experience. Do not change your dose or stop taking SERZONE without talking with your doctor first.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Your doctor has prescribed SERZONE for you and you alone. Do not give SERZONE to other people, even if they have the same condition. It may harm them.

This leaflet provides a summary of the most important information about SERZONE. If you would like more information, talk with your doctor or pharmacist. You can ask for information about SERZONE that is written for healthcare professionals. You can also get more information by visiting www.serzone.com.

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